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(54) CONTAINER FOR STERILE STORAGE OF LIQUID

(71) We, A/S HAUSTRUP PLASTIC., a Danish Company, of Industrivej 6, 5550 Langeskov, Denmark, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:-

This invention relates to a container for sterile storage of liquid, e.g. infusion liquid, rinsing liquid or the like, and in particular to devices associated with the container to prevent liquid in the container from being contaminated through direct or indirect contact with the outside atmosphere or contaminated objects prior to or during the use of the liquid from the container.

A container for storage of infusion liquid or rinsing liquid is often made of plastics material, and is fitted at one end thereof with a device by which it can be suspended and at the other end with a pointed tube intended for connection with a hose for removal of liquid from the container into, for instance, a hypodermic syringe which has been injected into a person's blood vessel. According to known technology, the pointed part is cut off by means of a tool in order to expose the interior of the tube. The tool in question is usually of a scissors-like type, which has been sterilized and which is intended to be used only once. It has turned out, however, that this scissors-like tool is sometimes used several times, which entails a risk of contamination of the tube at the point, and thus contamination of the liquid which comes from the container. There is also a risk of small particles of material being formed when cutting-off the point, which particles may be carried with the liquid when this leaves the container.

In connection with the supply of, for instance, infusion liquid there is often a need to add an additive liquid such as medicine, nutrient solution or the like. For this purpose it is usual to clean part of the container by means of alcohol and puncture the container by means of an injection needle, and then the desired additive liquid is supplied through this needle. When the injection needle has been taken out, the hole is sealed in the wall of the container by means of sterile tape. It is obvious that such a method involves a risk of contamination of the liquid in the container. In certain countries the risk is considered to be so great that the method in question has been prohibited.

When infusion liquid is supplied to a patient it is desirable to prevent low pressure in the system formed by the infusion liquid, drip chamber, hypodermic syringe and the hoses which connect the devices mentioned. The reason for this is that low pressure in the system will increase the risk that air is sucked into the system which may accidently have the effect that an air bubble is carried into the patient's blood vessel. In order to prevent such a low pressure, air (it can be sterile) is sometimes added purposely to the system. In connection with, for instance, infusion containers made of glass, the supply of air takes place through a connecting device in the opening of the container. In this way air bubbles will bubble up through the liquid in the container. Even this will involve a certain risk that an air bubble will remain in the liquid and be carried into the blood vessel of the patient.

In some countries it is therefore required that air shall be supplied direct to an air pocket which is situated in the container above the surface of the liquid, to equalize the pressure in the system with that of the ambient atmosphere. In connection with containers made of plastic material, this operation is also possible by penetrating the wall of the container using a suitable constructed penetrating device. The earlier mentioned drawbacks in connection with the penetration of the wall of the container and similar risks of unallowable contamination

are present, however, in this method and in connection with the containers used until now.

According to one aspect of the invention there is provided a container for sterile storage of liquid, comprising a chamber enclosed by a wall, a plurality of sealing devices each overlying an area of the container wall, which area is made of penetrable material, the sealing devices being capable of re-sealing the container when a device penetrating the wall of the container and the sealing device is withdrawn from its penetrating position.

According to a further aspect of the invention there is provided a container for the sterile storage of liquid, comprising a chamber enclosed by a wall made of penetrable material, a plurality of sealing devices each overlying an area of the container wall, the sealing devices being capable of re-sealing the container when a device penetrating the wall of the container and the sealing device is withdrawn from its penetrating position, and further comprising a conduit for supplying and/or draining liquid to and/or from the chamber, the conduit having a point of weakness so that it can be broken off at the point of weakness when liquid is to be removed from the chamber.

The container is preferably provided with a conduit so made that it can be broken off when liquid is to be removed from the container, and having a plurality of points of weakness formed by axially spaced incisions extending at least almost all the way around the entire periphery of the conduit, the point of weakness most remote from the chamber defining a limit to the end most part of the conduit for exposure of the interior thereof through breaking off the end most part. When there are several points of weakness these are arranged at axially spaced intervals such that the container when opened can be sealed again by heating the extreme end of the conduit and pressing the surfaces against each other for welding. The adjacent point of weakness will remain intact, and thus it can be used again for drawing liquid out of the chamber.

At least one of the sealing devices is preferably arranged near a suspending device for the container.

The invention will now be described, by way of example, with reference to the accompanying drawings, in which:-

Fig. 1 in perspective illustrates a container according to the invention,

Fig. 2 is a perspective view, partly in section, of the conduit of the container, and

Figs. 3*a* to 3*e*, in section, illustrate sealing devices.

Referring to the drawings, a container 1, Fig. 1, is provided with a suspension device 7 and with a conduit 2. The conduits is provided with a number of points of weakness 3, only one of which is shown in Fig. 1. An end portion 5 of the conduit 2 has one extremity thereof defined by the point of weakness, at which point 5 is connected to the rest of the conduit 2. Fig. 1 also shows how a hypodermic syringe 8 can have its needle 9 inserted into the container 1 through a sealing device 10. Other sealing devices are provided at suitable positions, such as at 16, close to the suspension device 7.

Referring to Fig. 2, the conduit 2 has a hollow interior 6 which is sealed at the lower end of the portion 5 of the conduit. In this way, the interior, or chamber, of the container and the interior 6 of the conduit form a sealed volume, which is completely sealed from contact with the surroundings. Fig 2 also illustrates how a point of weakness 3 has been arranged in the conduit, the point of weakness consisting of an inwardly directed incision 4 which extends at least almost all the way around the periphery of the conduit. The body of the container is connected to the conduit 2, by a neck provided with a number of beads 15 which co-operate with a removable protective cover. By means of this cooperation, the protective cover is kept in position over the conduit, which is thus prevented from breaking accidentally. The protective cover can be made according to known technical methods and therefore it has not been shown in the drawing.

Only one point of weakness 3 has been shown in Fig. 2 but it is possible to have a plurality of breaking incisions 4 spaced apart axially of the conduit 2. By allowing the axial distance between the incisions 4 to be sufficiently large, the container can be opened by breaking off the end most portion 5 of the conduit 2, and it can be re-sealed by heating the remaining extreme end of the portion 5 and pressing it together.

Figs. 3*a* to 3*e* illustrate various embodiments of sealing devices on the container each showing a different way in which the sealing device may be secured to the container wall. In each of these Figs. there is shown the wall 12 of the container and the sealing material 13, which latter may, for instance, consist of rubber.

In Fig. 3*a* the sealing device is a sealing material container 11 of rectangular cross-section in which the sealing material 13 is contained. The container 11 can be fixed against the wall 12 of the container 1 in several different ways. As shown in Fig. 3*a* the container 11 is provided with a flange or collar 14, which collar is fixed against the wall 12 of the container, for example by welding or glueing. Direct glueing or welding of the container 11 against the wall 12 or the container 1 will probably be possible.

In Fig. 3*b* the sealing material 13 is fixed against the wall 12 of the container 1 by means of a layer 17 of plastics material,

which is welded at cast over part of its area against the wall 12 of the container 1. The layer 17 of plastics material may be glued against the wall 12 of the container 1 instead of being welded. The advantage of fixing the sealing material to the wall of the container in this way is that fixing of the sealing material 13 to the layer 17 of plastics material can be performed in a separate operation, for which a higher pressure and a higher temperature can be used than is the case if the sealing device were secured directly against the wall of the container. In this way a good connection is obtained between the sealing material and the layer 17 of the plastics material. The joint between the layer 17 of the plastics material and the wall 12 of the container 1 can easily reach the required standard through welding or glueing.

In Fig. 3*c* the sealing material 13 has been fixed against the wall 12 of the container 1 by means of a glue joint 18.

In Figs. 3*d* and 3*e* the sealing material 13 has been inset into the wall 12 of the container 1 in a pocket having substantially a shape and size corresponding to the dimensions of the sealing material. The attachment of the sealing material can be effected by means of a layer 17 of plastics material Fig. 3*d* or by means of glue 18, Fig. 3*e* in the way described above. In the pockets there may be cracks or wrinkles, in which contamination can arise. These cracks or wrinkles are not easily accessible for cleaning. The inset material can therefore be covered by a protective layer 19 of plastics material in instances where there are special requirements of purity.

Even in the embodiments which are illustrated in Figs. 3*a* to 3*c* a protective layer 19 may be used. This protective layer can even be used as a means of fixing the sealing material to the container, and thus it will fully or partly replace the earlier mentioned means of securement. In this case the sealing material is palced aginst the wall 12 of the container 1 and a plastics foil 19 covering the sealing material and the wall 12 of the container 1 immediately round the sealing material will be welded or glued against the wall 12 of the container 1 and maybe even against the sealing material. The plastics foil can be made of a material which shrinks when it is heated, and through the shrinkage of the plastics foil it will be possible to fasten this tightly against the sealing material.

When a container according to the invention is used, it will be filled with the desired liquid and then the conduit 2 of the container is sealed at its end portion 5, usually by welding the extreme end of the end portion 5. The protective cover is fastened over the conduit and it is kept in position by means of the beads 15, and then the filled container is ready to be sent to the user.

In the cases when users want additive liquid, e.g. nutrient solution, supplied to the container, the sealing device 10 of the container is cleaned by means of a sterilizing liquid, and then the sealing device and the wall of the container are penetrated by the needle 9 of for instance a hypodermic syringe 8, and the desired quantity of solution is supplied to the inside of the container. Then the point of the needle is pulled out. The sealing material in the sealing device will immediately seal the opening made by the needle and thus contact is efficiently prevented between the surroundings and the inside of the container 1.

In the cases when pressure equalization is to be performed during the drawing of liquid the sealing device 16 which is situated closest to the suspending device 7 of the container 1 is penetrated by a flow device for gas, which, if necessary, is connected with a filtering device.

The protective cover over the conduit 2 of the container can then be removed. The end portion 5 of the conduit is broken off at the point of weakness 3 by applying force tm the end portion. The interior 6 of the conduit can then be connected to a hose for conveyance of liquid from the chamber of the container 1. In this way there will be least risk of contamination of the point of connection between the hose and the conduit of the container. The exposure of the conduit's interior 6 can also take place without the use of any exterior tools, which is also important as far as safety and convenience are concerned. In this way, the expense of special tools for opening the container is also avoided.

The material that is used in the wall 12 of the container 1 in the cases where the wall of the container is made of plastics material will obviously depend upon the medical requirements of the material. This even refers to the requirements for sterilization for instance through autoclave sterilization. The temperature of autoclave sterilization is different from country to country, and thus the mterial will have to be selected so that it will stand the temperature at which the autoclave sterilization takes place. Examples of plastics materials which are suitable for this purpose are polypropylene, polythene, and PVC. The durability properties of the various materials will determine the angle between the walls of the incision 4, which form the point of weakness for separation of the end portion 5 of the conduit 2. Depending upon the material used, the angle can vary between about 50° and 80°. Using polypropylene, it has for instance been found suitable to have a value for the angle of between 60° and 80°, and thus an angle of 70° has mainly been used.

It is obvious that both the design of the sealing device are such that both of the

devices can be used independently of each other, but both of these devices in combination contribute considerably to a higher degree of safety in connection with the use of for instance infusion liquid or rinsing liquid. In addition to storage of infusion liquid, the containers made according to the invention can also be used in other medical connections, e.g. for storage of rinsing liquid, blood serum, blood, and such things.

Although the sealing devices are shown in the accompanying drawings as being on the outside of the container wall, the sealing devices could equally well be disposed to overlie the internal surface of the wall of the container.

WHAT WE CLAIM IS:-

1. A container for sterile storage of liquid, comprising a chamber enclosed by a wall, a plurality of sealing devices each overlying an area of the container wall, which area is made of penetrable material, the sealing devices being capable of re-sealing the container when a device penetrating the wall of the container and the sealing device is withdrawn from its penetrating position.

2. A container as claimed in Claim 1, in which the penetrable material is plastics.

3. A container as claimed in any preceding claim, in which at least one sealing device is arranged near a suspending device for the container.

4. A container as claimed in any preceding claim, in which the sealing devices are fixed against the wall of the container by means of a layer of plastics material.

5. A container as claimed in any of Claims 1 to 3, in which the sealing devices are fixed against the wall of the container by means of a layer of glue.

6. A container as claimed in any preceding claim, in which the sealing devices are arranged in pockets in the wall of the container.

7. A container as claimed in any of claims 1 to 5, in which the sealing devices comprise sealing material containers which are fastened to the wall of the container and are filled with sealing material.

8. A container as claimed in any preceding claim, in which plastics foil covers each sealing device and a portion of the container wall surrounding that area of the wall overlain by the sealing deivce.

9. A container as claimed in Claim 8, in which edges of the plastic foil are fixed against the said portion of the container wall, thereby at least contributing to the fixing of the sealing devices to the container wall.

10. A container as claimed in Claim 9, in which the edges of the plastic foil are fixed by welding or glueing.

11. A container as claimed in any preceding claim, in which the sealing devices are made of rubber.

12. A container as claimed in any preceding claim, in which the sealing devices are disposed on the outside of the wall of the container.

13. A container as claimed in any of Claims 1 to 11, in which the sealing devices are disposed on the inside of the wall of the container.

14. A containter as claimed in any preceding claim, in which the container is provided with a conduit for supplying and/or draining liquid to and/or from the chamber, the conduit being so made that it can be broken off when liquid is to be removed from the chamber.

15. A container as claimed in Claim 14, in which the conduit is provided with a plurality of axially spaced points of weakness, each comprising an incision extending at least almost all the way around the entire periphery of the conduits, the point of weakness most remote from the chamber defining a limit to an end portion of the conduit, which end portion can be broken off to expose the interior of the conduit.

16. A container as claimed in Claim 15, in which the axial distance between points of weakness is such that, when the container has been opened, it can be re-sealed by heating the end of the conduit most remote from the chamber and pressing together that end so that the container is sealed and can be opened against by breaking off the conduit at another point of weakness.

17. A container as claimed in Claim 15 or 16, in which the angle between the sides of each incision is between 50° and 80°.

18. A container as claimed in Claim 17, in which the angle is 70°.

19. A container as claimed in any of Claims 14 to 18, in which the conduit has, adjacent the wall of the container, a portion provided with a plurality of beads arranged to co-operate with a protective cover in such a way that the protective cover is kept in position around the conduit, thereby preventing exposure of the conduit to a breaking force.

20. A container for the sterile storage of liquid, comprising a chamber enclosed by a wall made of penetrable material, a plurality of sealing devices each overlying an area of the container wall, the sealing devices being capable of re-sealing the container when a device penetrating the wall of the container and the sealing device is withdrawn from its pentrating position, and further comprising a conduit for supplying and/or draining liquid to and/or from the chamber, the conduit having a point of weakness so that it can be broken off at the point of weakness when liquid is to be removed from the chamber.

21. A container for the sterile storage of liquid substantially as hereinbefore described with reference to the accompany-

ing drawings.

PAGE WHITE & FARRER
Chartered Patents Agents,
27 Chancery Lane,
London WC2A 1NT
Agents for the Applicants

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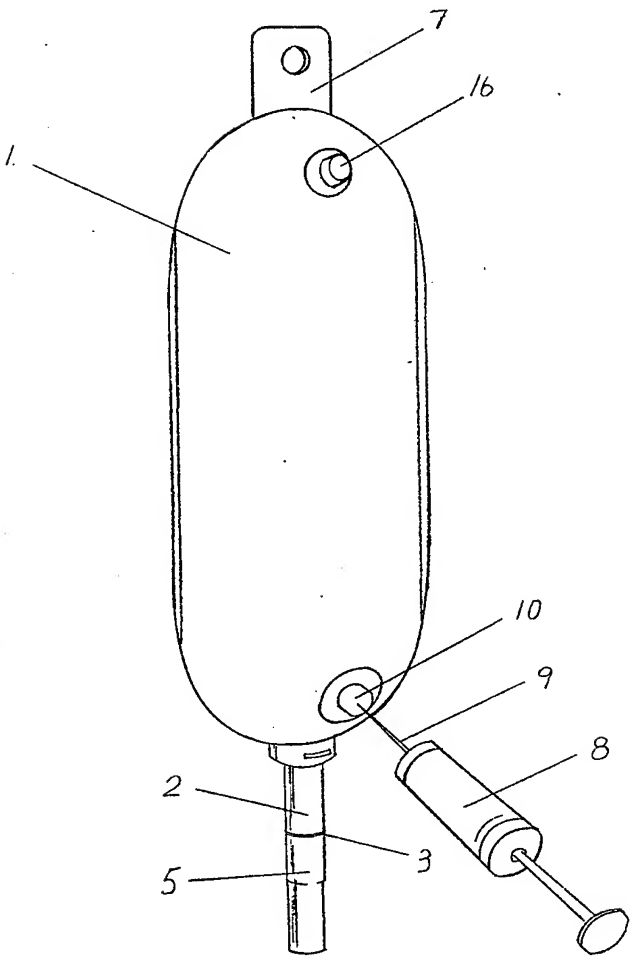
1579065 COMPLETE SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1

Fig 1



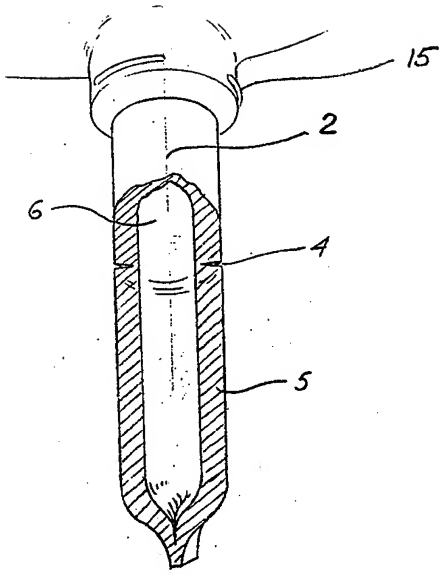


Fig. 2

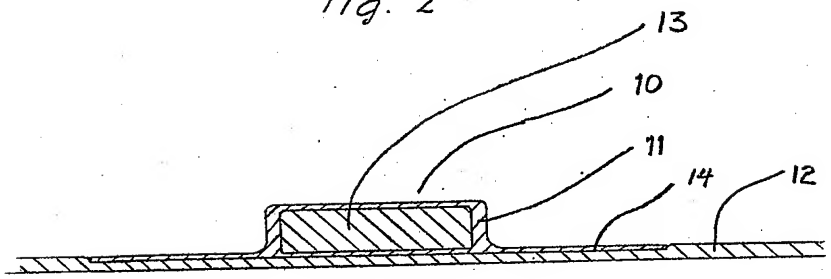


Fig. 3a

Fig 3b

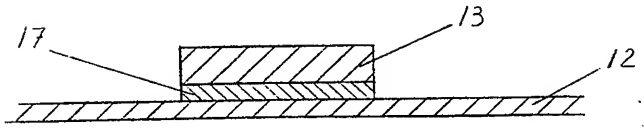


Fig 3c

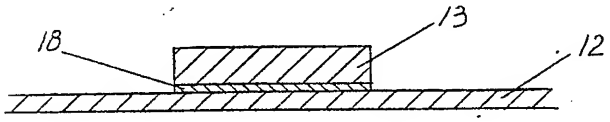


Fig 3d

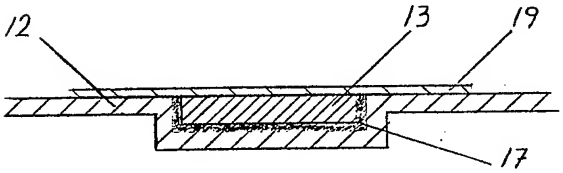


Fig 3e